

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL-TYPE SEARCH REPORT

(PCT Article 15.5)

National application No. 9802073-8	Country or Office of filing SE	Applicant's or agent's file reference D 1576-1 SE
Filing date (day/month/year) 11 June 1998		(Earliest) Priority Date (day/month/year)
Applicant Astra Aktiebolag		

Date of request for international-type search 11 June 1998	International-type search request No. SE 98/00582
---------------------------------------------------------------	------------------------------------------------------

This international-type search report has been prepared by this International Searching Authority and is transmitted to the applicant.

This international-type search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☒ Certain claims were found unsearchable (See Box I).
2. ☐ Unity of invention is lacking (See Box II).
3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international-type search was carried out on the basis of the sequence listing
  - ☐ filed with the international application.
  - ☐ furnished by the applicant separately from the international application,
    - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
  - ☐ transcribed by this Authority.

# INTERNATIONAL-TYPE SEARCH REPORT

Search request No.

SE 98/00582

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international-type search report has not been established in respect of certain claims for the following reasons:

1. ☒ Claims No.: 5-8  
because they relate to subject matter not required to be searched by this Authority, namely:  
  
Claims 5-8 relates to methods of treatment of the human or animal body by surgery or by therapy/diagnostic methods practised on the human or animal body/ Rule. 39.1.(iv). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the compounds/compositions.
2. ☐ Claims No.:  
because they relate to parts of the national application that do not comply with the prescribed requirements to such an extent that no meaningful international-type search can be carried out, specifically:

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international-type search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international-type search report covers only those claims for which fees were paid, specifically claims No.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international-type search report is restricted to the invention first mentioned in the claims, it is covered by claims No.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL-TYPE SEARCH REPORT

Search request No.

SE 98/00582

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61K 31/57 // A61K 31/57, 31:165

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61K, C07J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CAPLUS, EPODOC, WPI

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9311773 A1 (AKTIEBOLAGET ASTRA), 24 June 1993 (24.06.93)	1-8
	--	
X	THE NEW ENGLAND JOURNAL OF MEDICINE, Volume 337, No 20, November 1997, Romain A. Pauwels et al, "Effect of inhaled formoterol and budesonide on exacerbations of asthma", page 1405 - page 1411, see page 1409-1410	1-8
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☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

### \* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international-type search

16 December 1998

Date of mailing of the international-type search report

1998 -12- 23

Name and mailing address of the ISA/  
Swedish Patent Office  
Box 5055, S-102 42 STOCKHOLM  
Facsimile No. +46 8 666 02 86

Authorized officer

Anna Sjölund  
Telephone No. +46 8 782 25 00

INTERNATIONAL-TYPE SEARCH REPORT  
Information on patent family members

01/12/98

Search request No.

SE 98/00582

WO	9311773	A1	24/06/93	AU	673660	B	21/11/96
				AU	3085892	A	19/07/93
				CA	2123909	A	24/06/93
				CZ	9401434	A	15/12/94
				EP	0613371	A	07/09/94
				HR	921445	A	31/12/94
				HU	75156	A	28/04/97
				HU	9401843	D	00/00/00
				JP	7502036	T	02/03/95
				NO	942116	A	07/06/94
				NZ	246050	A	21/12/95
				SG	48301	A	17/04/98
				SK	73394	A	08/03/95
				US	5674860	A	07/10/97

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REC'D 09 OCT 2000

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

PCT  
RECEIVED

(PCT Article 36 and Rule 70)

DEC 08 2000

Applicant's or agent's file reference D 1576-1 WO	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/ISA/160/2900)	
International application No. PCT/SE99/01031	International filing date (day/month/year) 10.06.1999	Priority date (day/month/year) 11.06.1998
International Patent Classification (IPC) or national classification and IPC A 61 K 31/57 // (A61K 31/57, 31/165)		
Applicant AstraZeneca Aktiebolag et al] ASTRAZENECA AB		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  22.12.1999	Date of completion of this report  25.09.2000
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer  Anna Sjölund/GH Telephone No. 08-782 25 00

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01031

## I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

☒ the international application as originally filed.

☐ the description, pages \_\_\_\_\_, as originally filed,  
 pages \_\_\_\_\_, filed with the demand,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☐ the claims, Nos. \_\_\_\_\_, as originally filed,  
 Nos. \_\_\_\_\_, as amended under Article 19,  
 Nos. \_\_\_\_\_, filed with the demand,  
 Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☐ the drawings, sheets/fig \_\_\_\_\_, as originally filed,  
 sheets/fig \_\_\_\_\_, filed with the demand  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/fig \_\_\_\_\_

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01031

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 13-24

because:

☒ the said international application, or the said claims Nos. 13-24  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv): Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01031

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	<u>1-12</u>	YES
	Claims	_____	NO
Inventive step (IS)	Claims	_____	YES
	Claims	<u>1-12</u>	NO
Industrial applicability (IA)	Claims	<u>1-12</u>	YES
	Claims	_____	NO

## 2. Citations and explanations

Claims 1-12 relate to the use of a composition for the manufacture of medicaments with specific medical qualities (so-called "second medical indication"). Claims of this kind may be accepted and examined in some countries. Owing to the differences in national practice and laws, it is not possible for the International Preliminary Examining Authority to give a valid statement on such claims. The consideration given is based on the acceptance of such claims according to national legislation.

Following documents are cited in the search report:

A) WO 93/11773 A1

B) "Effect of inhaled formoterol and budesonide on exacerbations of asthma", Löfdahl et al., The New England Journal of Medicine, vol 337, no.20, (1997), page 1405-11.

From A it is already known that the pharmaceutical combination of formoterol and budesonide has effect in the treatment of respiratory disorders, e.g. asthma, see page 4, line 20-21. In the second paragraph, page 2, lines 3-12, the need for immediate symptom relief is discussed. Combining formoterol with budesonide will then, according to the citation A, at the same time provide rapid relief of symptoms as prophylactic therapy.

In view of A, it seems obvious for a person skilled in the art, to use the composition as in claims 1-12, for preventing or treating acute conditions of the known indication asthma.

.../...



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01031

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V

Reference is also made to citation B, which discloses addition of formoterol to budesonide treatment. This resulted in reduced rates for severe and mild exacerbations.

Claims 1-12 therefore are considered to meet the requirements of novelty and to be industrially applicable, but the claims 1-12 are not considered to meet the requirements of inventive step.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE99/01031

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

The expression "episodes in chronic asthma" in claim 1 is not clear and concise and does therefore not meet the requirements of Article 6 PCT.

09/367950

1614

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0500

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

ASTRAZENECA AB  
Intellectual Property, Patents  
S-151 85 Södertälje  
SUÈDE**RECEIVED**

MAY 11 2000

TECH CENTER 1500/2300

Date of mailing (day/month/year) 05 April 2000 (05.04.00)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference D 1576-1 WO	
International application No. PCT/SE99/01031	International filing date (day/month/year) 10 June 1999 (10.06.99)

1. The following indications appeared on record concerning:	
<input checked="" type="checkbox"/> the applicant	<input type="checkbox"/> the inventor <input type="checkbox"/> the agent <input type="checkbox"/> the common representative
Name and Address ASTRA AKTIEBOLAG S-151 85 Södertälje Sweden	State of Nationality SE
	State of Residence SE
	Telephone No.
	Facsimile No.
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:	
<input type="checkbox"/> the person	<input checked="" type="checkbox"/> the name <input type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence
Name and Address ASTRAZENECA AB S-151 85 Södertälje Sweden	State of Nationality SE
	State of Residence SE
	Telephone No.
	Facsimile No.
3. Further observations, if necessary: <b>Please note that the above change also refers to the name indicated in box no. IV of the request form.</b>	
4. A copy of this notification has been sent to:	
<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Beatriz Morariu Telephone No.: (41-22) 338.83.38
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NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

ASTRAZENECA AB  
Intellectual Property, Patents  
S-151 85 Södertälje  
SUÈDE

RECEIVED

DEC 08 2000

TECH CENTER 1800/26

Date of mailing (day/month/year) 25 September 2000 (25.09.00)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference D 1576-1 WO	
International application No. PCT/SE99/01031	International filing date (day/month/year) 10 June 1999 (10.06.99)

## 1. The following indications appeared on record concerning:

☒ the applicant
     
 ☒ the inventor
     
 ☐ the agent
     
 ☐ the common representative

Name and Address EKSTRÖM, Tommy Astra Draco AB P.O. Box 34 S-221 00 Lund Sweden	State of Nationality SE	State of Residence SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

## 2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person
     
 ☐ the name
     
 ☒ the address
     
 ☐ the nationality
     
 ☐ the residence

Name and Address EKSTRÖM, Tommy AstraZeneca R&D Lund S-221 87 Lund Sweden	State of Nationality SE	State of Residence SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

## 3. Further observations, if necessary:

## 4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Mougamadou ABIDINE Telephone No.: (41-22) 338.83.38
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From the INTERNATIONAL BUREAU

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C. 20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year)

10 February 2000 (10.02.00)

International application No.

PCT/SE99/01031

Applicant's or agent's file reference

D 1576-1 WO

International filing date (day/month/year)

10 June 1999 (10.06.99)

Priority date (day/month/year)

11 June 1998 (11.06.98)

Applicant

EKSTRÖM, Tommy

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

22 December 1999 (22.12.99)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Beatriz Morariu

Telephone No.: (41-22) 338.83.38